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IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW JERSEY

MAY 11 2010

AT 8:30
WILLIAM T. WALSH
CLERK

SCHERING CORPORATION,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

Civil Action No. 09-6373 (GEB) (TJB)

DISCOVERY CONFIDENTIALITY ORDER

WHEREAS the Plaintiff, Schering Corporation (Schering), and the Defendants, Apotex Inc. and Apotex Corp. (collectively, Apotex), possess confidential information which may be disclosed in providing initial disclosures, responding to discovery requests, or otherwise in these proceedings, and which must be protected in order to preserve the legitimate business interests of the parties, and

WHEREAS good cause exists for entry of this Order, *see* Fed. R. Civ. P. 26(c), *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994);

WHEREAS all parties in their business practices have gone to great lengths to safeguard and protect the confidentiality of the documents and information and the disclosure of which would pose a substantial risk of irreparable harm to the producing party's legitimate proprietary interests, *see* Declaration of James Gould in Support of Request for Discovery Confidentiality Order on behalf of Schering, attached as Exhibit A; *see also* Declaration of Shashank Upadhye, Esq. in Support of Request for Discovery Confidentiality Order on behalf of Apotex, attached as Exhibit B;

WHEREAS this Discovery Confidentiality Order provides reasonable restrictions on the disclosure of such sensitive materials of a confidential nature;

WHEREAS all parties agree to the terms of this Discovery Confidentiality Order to protect their confidential documents and information;

WHEREAS to streamline the discovery process and minimize the need for Court intervention, this Discovery Confidentiality Order adopts an “umbrella” approach that allows the producing party to designate certain materials being produced or deposition testimony as confidential. Disclosure of materials designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” is limited to specific classes of persons;

WHEREAS this Discovery Confidentiality Order provides for filing confidential documents with the Court under seal, in accordance with the applicable rules and procedures, if such documents need to be filed as part of motion practice or in connection with other aspects of these proceedings;

WHEREAS this Discovery Confidentiality Order also provides that the party requesting production of the information may challenge the producing party’s confidentiality designation before the Court, thereby minimizing the likelihood that non-sensitive documents will be unnecessarily designated as confidential;

WHEREAS this Order allocates to the producing party the burden of justifying the confidentiality designation and umbrella orders of this type have been approved by the United States Court of Appeals for the Third Circuit, *see Pansy*, 23 F.3d at 787 n.17, *Cippollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1122 (3d Cir. 1986), *cert denied*, 484 U.S. 976 (1987);

THEREFORE, in view of the foregoing and because the parties hereto, by and through their respective counsel, have stipulated to the entry of the following Discovery Confidentiality

Order pursuant to Fed. R. Civ. P. 26(c), and the Court having reviewed the Declaration of James Gould on behalf of Schering and the Declaration of Shashank Upadhye, Esq. on behalf of Apotex, and the Court having determined that good cause exists for the entry of this Order,

IT IS HEREBY STIPULATED AND ORDERED THAT:

1. Definitions

(a) The term "Confidential Information" includes all confidential, private, product, business, commercial, or financial information and all information of a proprietary business or technical nature that the designating party believes might be of value to an actual or potential competitor of the designating party and that the designating party reasonably believes should be protected from disclosure.

(b) The term "Highly Confidential Information" shall mean information that the designating party believes, in good faith, the disclosure of which may cause harm to the competitive position of the designating party. Examples of such information may include without limitation:

- 1) Current and future business plans, including unpublished financial data and pricing information;
- 2) Private product development and design information (for new, old, suspended, and abandoned projects), including, in particular, formulation, bioavailability, stability or characterization information for drug products currently in development or for drug products the development of which has been suspended or abandoned;
- 3) New business development (for new and old projects);
- 4) Trade secrets;
- 5) Competitor market analysis;
- 6) Customer lists;
- 7) Distributor and supplier agreements and licenses;

- 8) Agreements with sales representatives;
- 9) Business relationships with third parties;
- 10) Manufacturing processes for products currently offered or under development, or for products the development of which has been suspended or abandoned, including, but not limited to, API syntheses, finished dosage form processes, or assays;
- 11) Confidential FDA filings, filings or submissions to the United States Pharmacopeia and other confidential regulatory material; and
- 12) Non-published patent applications.

(c) The term "Protected Information" shall mean information designated as containing or comprising Confidential or Highly Confidential Information pursuant to the provisions of this Order. It may include, without limitation, documents produced in this action or in any other actions between the Parties over the subject matter in suit, during formal discovery or otherwise; information produced by non-parties which the producing or designating party is under obligation to maintain in confidence; answers to interrogatories and responses to requests for admission or other discovery requests; deposition, hearing, or trial transcripts; and tangible things or objects that are designated as containing or comprising Confidential or Highly Confidential Information. The information contained therein and all copies, abstracts, excerpts, analyses, or other writing that contain, reflect, reveal, suggest, or otherwise disclose such information shall also be deemed Protected Information. Information originally designated as Protected Information shall not retain that status after any ruling by the Court denying such status to it.

(d) The term "designating party" means the party designating documents or information as Protected Information under this Order;

(e) The term “receiving party” shall mean the party to whom the Protected Information is disclosed.

(f) Notwithstanding anything to the contrary herein, the description Protected Information shall apply to all that information so designated by the designating party absent an order of the Court or subsequent written agreement of the designating party providing otherwise.

**Designation of Confidential or Highly Confidential
Information as Protected Information**

2. Each designating party who produces or discloses any material that it believes contains or comprises Confidential or Highly Confidential Information shall designate the same as Protected Information. In so designating the material, the designating party shall mark “CONFIDENTIAL” on any document containing Confidential Information and “HIGHLY CONFIDENTIAL” on any document containing Highly Confidential Information. When documents or things are produced for inspection, the documents or things may be collectively designated as containing Confidential Information for purposes of the inspection, by letter or otherwise, without marking each document or thing “CONFIDENTIAL,” and such documents or things will be treated as Protected Information under this Order.

3. If any Confidential or Highly Confidential Information is produced by a non-party to this litigation, such a non-party shall be considered a “designating party” within the meaning of that term as it is used in the context of this Order and both parties to this Order should be treated as receiving parties. The parties recognize that, during the course of this litigation, Confidential or Highly Confidential Information that originated with a non-party, and for which there exists an obligation of confidentiality, may be produced. Such information that the designating party believes originated with a non-party, but is subject to a confidentiality

obligation may be designated as Protected Information and shall be subject to the restrictions of disclosure specified in Paragraph 5.

4. In the event any designating party discovers, after it has produced information, that it has inadvertently produced Confidential or Highly Confidential Information that has not been correctly designated, the designating party may redesignate the information by a subsequent notice in writing specifically identifying the redesignated information, in which event the parties shall henceforth treat such information in accord with this Discovery Confidentiality Order, and shall undertake reasonable efforts to correct any disclosure of such information contrary to the redesignation.

5. Information designated "Confidential Information" may be disclosed only to the following:

(a) outside counsel for the receiving party, and the secretarial, clerical, paralegal, and other supporting personnel of said outside counsel; at present, such outside counsel are Weil, Gotshal & Manges LLP; Gibbons P.C.; Rakoczy Molino Mazzochi Siwik LLP; and Saiber LLC; but this provision shall include any other law firms whose attorneys enter an appearance;

(b) the following in-house counsel and representatives employed by the parties:

- 1) for Schering: Paul D. Matukaitis, Esq., Edward W. Murray, Esq., and James M. Gould, Esq.
- 2) for Apotex: Shashank Upadhye, Esq.

(c) independent consultants or experts (and their staff) retained by the attorneys for the parties, either as technical consultants or expert witnesses for the purposes of

this litigation, as long as the consultants or experts comply with the procedure of Paragraph 8 herein;

(d) witnesses testifying during a deposition or at trial, if the witness is a current or former director, officer, or employee of the designating party, so long as:

- 1) such examination concerns Protected Information that the witness authored or previously had access to or knowledge of, as demonstrated by the Protected Information itself or by foundational testimony during a depositions, hearing, or trial, or the witness was employed by the designating party during the relevant time and is reasonably believed to have had access to the Protected Information, and
- 2) in the case of a former director, officer, or employee, the witness agrees to be bound by and signs a copy of the Declaration of Compliance attached hereto as Exhibit C, unless the designating party otherwise agrees to such disclosure without such signed written assurance;

(e) non-technical trial consultants and graphics or design firms retained by outside counsel for the receiving party for the purpose of preparing demonstrative or other exhibits, including their supporting personnel;

(f) licensed court reporters and videographers employed in connection with this case; and

(g) the Court and its authorized personnel.

The foregoing list in this Paragraph 5 may be expanded by mutual agreement in writing by counsel for Plaintiff and Defendants. In addition, to the extent that any of the in-house counsel listed above is replaced during the course of this litigation, replacement counsel may be substituted in this Order.

6. Information designated "Highly Confidential Information" may be disclosed only to persons described in Paragraphs 5(a) and (c) – (g) above.

7. In the event that a receiving party desires to provide access to Protected Information to any person not otherwise entitled to such access under this Order, the receiving party shall first request in writing an agreement to do so from the designating party. If the designating party refuses to enter into such an agreement within ten (10) business days, the receiving party may move the Court for an order that such person be given access thereto. In the event that the motion is granted, such person may have access to Protected Information only after having signed an undertaking in the form of the Declaration of Compliance attached hereto as Exhibit C, a copy of which shall be forwarded promptly to the designating party, or under such other conditions as the parties to the case may agree or the Court may order.

Use and Control of Protected Information

8. Before an expert or consultant is afforded access to another party's Protected Information, the identity, current resume, or curriculum vitae of the expert shall be furnished to the designating party along with a signed Declaration of Compliance, a copy of which is attached hereto as Exhibit C. The resume or curriculum vitae and signed Declaration of Compliance may be provided at any time after this Discovery Confidentiality Order is signed by the parties. The parties will then have ten (10) business days from the date of receipt of the name and resume or curriculum vitae of the expert or consultant, during which time counsel for the designating party may object in good faith to the disclosure of Protected Information to the expert or consultant for cause, *e.g.*, an identified conflict of interest. If counsel for the designating party fails to object to such disclosure within the prescribed period, any objection to such disclosure shall be waived, except as to the basis for objection that was not known and could not reasonably have been discovered within said ten day period. In the event that a good faith objection is made within the ten day period, there shall be no disclosure of Protected Information to the expert or consultant

until there is an express written agreement of the parties or order of the Court removing the objection. If the issue cannot be resolved, the designating party may, within ten (10) business days after service of the objection, bring a motion to preclude the expert or consultant from viewing the designating party's Protected Information. If the designating party does not bring such a timely motion, Protected Information may be disclosed by the receiving party to the retained expert or consultant.

9. All information properly designated as Protected Information pursuant to this Order and disclosed in this litigation shall be used by a recipient thereof solely for the purposes of this litigation and not for any business or competitive purposes, including but not limited to any communications or submissions to USPTO, FDA or the United States Pharmacopeia. It shall be the duty of each party and each individual having notice of this Discovery Confidentiality Order to comply with this Order from the time of such notice. Protected Information may be used, relied upon, and referred to in any testimony or other evidence presented at any trial, hearing, or deposition conducted in connection with this case, so long as the person presenting such testimony or evidence is authorized to have access to such Protected Information under the terms of this Order, and subject to any further order of the Court regarding confidentiality.

10. All deposition testimony shall be marked Highly Confidential and shall be treated as containing Protected Information and subject to this Order until a time thirty (30) calendar days after the official transcript of such testimony is received. Thereafter, the information contained in the deposition transcript will no longer be deemed Protected Information unless:

(a) in a writing sent to counsel for the receiving party before the expiration of the thirty day period, counsel for the designating party claims in good faith that the deposition transcript (or a specified portion of it) contains Protected Information; or

(b) at the deposition, counsel for the designating party stated on the record that certain portions of the deposition transcript contain Protected Information.

11. If during a Court proceeding Confidential or Highly Confidential Information is likely to be revealed, any party may request that the proceeding be held *in camera*. If such request is granted by the Court, the transcript of such proceedings shall be treated as a deposition transcript for the purposes of this Order.

12. Motions to Seal Or Otherwise Restrict Public Access to Materials and Judicial Proceedings shall be handled as follows:

(a) If a party intends to file with the Court or the Clerk's office its own Protected Information (a Filed Disclosure), or if a party intends to reveal its own Protected Information during a Court hearing or trial which is otherwise open to the public (a Public Disclosure), the party may file a motion to seal or otherwise restrict public access to the relevant Protected Information in accordance with Local Civil Rule 5.3(c).

(b) Any party filing with the Court any material that has been designated Protected Information by another party, shall comply with the requirements of Local Rule 5.3, and shall simultaneously file a Motion to Seal such Protected Information in accordance with the provisions of Local Civil Rule 5.3, to prevent public disclosure; provided however, that:

- 1) the burden of proving to the Court that such Protected Information should be sealed under Local Civil Rule 5.3 shall at all times remain with the party that initially produced the material and designated it as Protected Information, and the designating party shall be responsible for filing supplemental motion papers pursuant to Local Civil Rule 5.3(c)(2), and

- 2) if the party filing the material is not the designating party, the filing party nonetheless is obligated to make a reasonable effort when filing Protected Information to meet the provisions of Local Civil Rule 5.3 to protect the designating party's materials.

The requirements of this paragraph shall not apply to informal discovery dispute submissions delivered directly to the Magistrate Judge without being filed on the Court's public docket.

13. A party seeking to file with the Court any document or thing containing or embodying any confidential materials or referring to such material, including deposition transcripts, answers to interrogatories, briefs, memoranda, affidavits, and the like, shall make a formal motion to the Court to file such document or thing under seal pursuant to Loc. Civ. R. 5.3(c)(1). Only the protected portions of filings with the Court shall be filed under seal. This material shall be, in the first instance, electronically filed as provisionally sealed, and its caption shall bear the notation of "SUBJECT TO MOTION TO SEAL".

14. If a third party provides discovery to any party in connection with this action, and if the third party so elects, then the provisions of this Discovery Confidentiality Order shall apply to such discovery and the parties will treat all information that is produced by such third party and designated as Confidential or Highly Confidential Information in accordance with the terms of this Discovery Confidentiality Order. Under such circumstances, the third party shall have the same rights and obligations under this Discovery Confidentiality Order as held by the parties to this action.

Miscellaneous

15. This Discovery Confidentiality Order is intended to provide a mechanism for handling the disclosure or production of Confidential or Highly Confidential Information to which there is no objection other than confidentiality. Each party reserves the right to object to

any disclosure of information or production of any documents it deems to contain Confidential or Highly Confidential Information on any other ground it may deem appropriate, and any party may move for relief from, or general or particular modification of, the mechanism herein set forth or the application of this Order in any particular circumstance.

16. This Discovery Confidentiality Order may be amended with respect to specific documents or items of Protected Information by Court order, or by written agreement of the parties hereto. This Discovery Confidentiality Order shall remain in force and effect indefinitely until modified, superseded, or terminated by Order of this Court.

17. Upon final termination of this action (including all appeals) with respect to any party receiving any Protected Information and at the option of the designating party, the receiving party shall, within thirty (30) days of such termination, either return to the designating party or destroy all Protected Information in its possession. In either event, the receiving party shall certify their return or destruction, with the exception that outside counsel for each party may retain copies of each of: the pleadings or other papers filed with the Court or served in the course of the litigation, the depositions, the deposition exhibits, and the trial record.

18. No party or person shall disclose or cause to be disclosed to anyone not specified in Paragraph 5 as being entitled to receive it, any information designated as Protected Information under this Discovery Confidentiality Order without prior written consent of the designating party or an Order of this Court. If the receiving party learns that Protected Information produced to it is disclosed to any person other than in the manner authorized by this Order, the receiving party learning of the disclosure must immediately inform the designating party of all pertinent facts relating to such disclosure and shall make every effort to prevent disclosure by each unauthorized person who received such information.

19. No expert or consultant designated in accordance with Paragraph 5(c) above shall have access to Protected Information without first signing a Declaration of Compliance with the Discovery Confidentiality Order, in the form attached hereto as Exhibit C, and meeting the requirements of Paragraph 8. A file of all such original written Declarations shall be maintained by counsel for the party obtaining them.

20. Nothing herein shall prevent any party or non-party from seeking additional relief from the Court not specified in this Order.

21. Nothing herein shall prevent: (a) any party from disclosing its own Protected Information in any manner that it considers appropriate or (b) the disclosure of Protected Information to any person who either authored in whole or in part, or who received in the ordinary course of his or her work, the Protected Information.

22. Nothing herein shall prevent a receiving party from contending (for the purposes of securing an order so providing from the Court) that any or all Protected Information is not confidential or otherwise not entitled to protection. Any receiving party may at any time request that the designating party cancel or change the Protected Information designation with respect to any document, object or information. Prior to moving the Court for an order that materials designated as Protected Information be redesignated, however, the receiving party shall first request in writing that the producing party change or remove its confidentiality designation. If the designating party refuses to change its confidentiality designation within ten (10) business days from the request, the receiving party may move for an order changing or removing the designation. On such a motion, the receiving party shall have the burden of proving that the material designated as Protected Information embodies information that does not fall within the scope of Protected Information as defined herein.

23. The parties have agreed that inadvertent production of documents or information subject to the attorney-client privilege, work product immunity, or any other applicable privilege (despite the parties' reasonable efforts to prescreen such documents and information prior to production) does not waive the attorney-client privilege, work product immunity, or other privilege if a request for return of such documents or information is made promptly after the producing party learns of its inadvertent production. Within three (3) business days of receiving a written request to do so from the designating party, the receiving party shall return to the designating party any documents or tangible items that the producing party represents are covered by a claim of attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The receiving party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information. The receiving party may thereafter contest such claims of privilege or immunity as if the materials had not been produced; but in contesting such claims, the receiving party shall not rely on any portion of the document other than the description set forth in the designating party's privilege log as per Fed. R. Civ. P. 26(b)(5). The receiving party shall not assert that a waiver occurred as a result of the inadvertent production.

24. The parties agree that (a) drafts of expert reports and working notes in connection with the preparation of expert reports are not discoverable and need not be retained or produced; and (b) communications between an expert for a party and that party's attorneys are not discoverable, except to the extent that the expert relied upon any such communications as a basis or grounds for any opinion to be expressed by the expert in any direct or rebuttal testimony. In all other respects, the parties and their experts shall fully comply with the disclosure requirements of Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure.

25. This Order shall continue in effect after termination of this action and continue to be binding upon all persons to whom Protected Information is disclosed hereunder.

26. Until such time as this Order has been entered by the Court, the Parties agree that upon execution by the Parties, it will be treated as though it had been "So Ordered."

**We hereby consent to the form
and entry of this Discovery Confidentiality Order.**

By: _____	By: _____
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For good cause shown, it is so ordered.

Dated this 10 day of May, 2010.


HON. TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE